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Attorney Docket No. 8465/43

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Lasse W. Mogensen, et al.	:	
Serial No.:	10/813,214	:	Confirmation No.: 5131
Filed:	March 29, 2004	:	Group Art Unit: 3767
For:	INJECTOR DEVICE FOR PLACING A SUBCUTANEOUS INFUSION SET	:	Examiner: Elizabeth Moulton

APPEAL BRIEF

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is in response to the Final Office Action mailed April 22, 2009[1].

[1] Appellants filed a Notice of Appeal on August 26, 2008 and an Appeal Brief on November 26, 2008. A Final Office Action was mailed on April 3, 2009. A second Notice of Appeal was filed on June 3, 2009. Appellants' transmittal filed with the second Notice of Appeal authorized charging the deposit account of the undersigned's firm in case additional fees were required and so the $30 due for the second Notice of Appeal is believed to have been paid ($510 was previously paid for the Notice of Appeal filed on August 26, 2008). Since the present Appeal Brief is being filed within two months of the date of receipt of the second Notice of Appeal, the present Appeal Brief is timely filed.

I. REAL PARTY IN INTEREST

Unomedical A/S, a ConvaTec Company, which is owned by Nordic Capital and Avista Capital Partners, is the real party of interest in this Appeal.

II. RELATED APPEALS AND INTERFERENCES

The undersigned, Heidi A. Dare, is aware of two appeals filed with the Board of Patent Appeals and Interferences that may be related to, would directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal. One appeal is pending and regards United States Patent Application Serial No. 10/687,568 ("the '568 application"). A Notice of Appeal was filed on June 5, 2009 regarding the '568 application. The present application is a continuation-in-part of the '568 application.

A second appeal is also pending that regards United States Patent Application Serial No. 11/031,635 ("the '635 application"), which is a continuation of the '568 application. A Notice of Appeal was filed on October 3, 2008 regarding the '635 application. The latest document filed was a Reply on June 16, 2009.

The undersigned is unaware of any other prior or pending appeal, interference, or judicial proceedings that may be related to, directly affect or be affected by, or have a bearing on the Board's decision in this Appeal.

III. STATUS OF CLAIMS

Claims 50-59, 65-72 and 78-100, all claims presented, are rejected and appealed. Claims 1-49 are canceled. Claims 60-64 are allowed. Claims 73-77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No claims are withdrawn from consideration.

IV. STATUS OF AMENDMENTS

Prior to the filing of the present Brief on Appeal to the Board of Patent Appeals and Interferences, an Amendment was filed on October 30, 2007 in response to a Final Office Action mailed on July 23, 2007. The Amendment was entered since it was filed concurrently with a Request for Continued Examination. A Supplemental Amendment was filed on December 10, 2007 which was considered.

No amendments were filed in response to the Final Office Actions mailed on May 13, 2008. An Appeal Brief was filed November 26, 2008. In response to the Appeal Brief, the Examiner issued another Final Office Action on April 3, 2009 in which the grounds for reopening prosecution are unclear to Appellants as the same art was cited. A Supplemental Final Office Action was mailed on April 22, 2009 at Appellant's request to clarify procedurally the actions taken by the Examiner. The Examiner issued the Final Office Action mailed April 22, 2009 after the filing of the Appeal Brief to clarify

the issues for appeal. Appellants expect that no additional Office Action will follow this Appeal Brief.

V. SUMMARY OF CLAIMED SUBJECT MATTER

1. Summary of Embodiments of Invention

An understanding of the invention of independent claims 50, 72, 90, 93, 97, 100 can be made upon a review of the embodiments of the invention shown in FIGS. 1-21e and 23a-b of the specification. Note that in the description to follow, like elements will employ identical identification numerals.

In accordance with the invention, FIGS. 1-5 show an injector device 10 that has an infusion set 14 with a cannula 26 extending therefrom (Page, 6 lines 29-32). The injector device 10 includes a plunger 30 having thereon a medical insertion needle 12 with a pointed end 12A (Page 7, lines 1-2). The plunger 30 is arranged for longitudinal sliding movement within a device housing 28 between a forward advanced position (FIG. 3 and 4) and a rearward retracted position (FIG. 1 and 2) (Page 7, lines 2-6). The device housing and the plunger 30 can be formed in a molding process (Page 7, lines 6-7).

The infusion set 14 is used to infuse medical fluids to a patient, and generally includes a housing with an internal chamber (not shown) that receives medication via infusion tubing (Page 7, lines 9-11). As shown in FIG. 1, a base 24 of the infusion set 14 is provided on the housing for stable affixation thereof to the skin of the patient (Page

7, lines 11-13). The base 24 may carry an adhesive and be provided with a release sheet 14' (FIG. 2) which is removed to expose the adhesive prior to placement of the infusion set (Page 7, lines 11-14). As shown in FIG. 1, the infusion set has a protruding soft and flexible cannula 26, which communicates with the internal chamber, and a passage sealed by a sealing membrane extends through the housing opposite the cannula 26 (Page 7, lines 16-19). As shown in FIGS. 1-2, the medical insertion needle 12 of the injector device 10 extends through the passage, into the internal chamber and through the cannula 26, when the infusion set 14 is mounted in position on the injector device (Page 7, lines 19-22). After transcutaneous placement of the cannula 26, the injector device 10 with the insertion needle 12 is retracted from the infusion set 14 to permit medication delivery through the cannula 26 to the patient (Page 7, lines 22-25).

The injector device 10 includes a trigger-type actuator mechanism for transcutaneous placement of the insertion needle 12 which is secured to the plunger 30, with the insertion needle 12 oriented at an angular position relative to the skin of the patient (Page 8, lines 11-14).

As shown in FIG. 3, the plunger 30 has a recessed head 32 at a lower or forward end thereof shaped for receiving the housing of the subcutaneous infusion set 14 (Page 8, lines 18-19). Centrally in the recess, the head 32 is provided with the metal insertion needle 12, which is securely connected thereto (Page 8, lines 20-21). As shown in FIG. 2, a rear end of the plunger 30 has a trigger-type actuator assembly 34 cooperating with the rear end of the device housing 28, and includes a stem, which is longitudinally split

to define a pair of trigger arms 38 which have outturned trigger fingers 58 on the sides thereof (Page 8, lines 28-32). As shown in FIGS. 1-2, the trigger actuator assembly 34 is adapted to hold the plunger 30 in a retracted position, against the force of a compressed helical drive spring 36 (Page 8, lines 32-34). The trigger arms 38 of the actuator assembly 34 are adapted for fingertip depression to release the plunger 30 for spring-loaded travel toward the advanced position, and for corresponding transcutaneous placement of the insertion needle 12, and of the cannula 26 travelling therewith, through the patient's skin (Page 8, line 34 – Page 9, line 4). In an alterative embodiment, release of the plunger 30 may be caused by pressing manually on diametrically opposed outside areas of the device housing 28 to deform the housing 28 and thereby effect release of the trigger arms 38 (Page 9, lines 4-7).

As shown in FIGS. 1-5, a hollow bore of the device housing 28 has a size and shape for reception of the infusion set 14, with the insertion needle 12 extending through the cannula 26 and extending together with the cannula 26 in a direction for placement on a patient (Page 9, lines 13-16). A releasable cover sheet 42 (FIGS. 1 and 2) is preferably secured to the device housing 28 at the nose end thereof to indicate the sterility of the infusion set 14 (Page 9, lines 16-18).

As shown in FIGS. 1-2, the trigger assembly 34 is initially locked against a shoulder 66 formed on the device housing 28 by the trigger fingers 58 (Page 10, lines 5-7). As shown in FIGS. 1-2, the drive spring 36 includes a coil spring positioned about the stem on the plunger 30 and reacts between a rearward face 64 of the plunger head

32, and an internal shoulder 66' on the device housing 28 (Page 10, lines 7-10). The drive spring 36 normally biases the plunger 30 toward the advanced position (Page 10, lines 10-11). In a retracted plunger position shown in FIG. 1, the drive spring 36 is retained in a compressed and cocked condition, with the cannula 26 of the infusion set 14 being received on the insertion needle 12 (Page 10, lines 14-16). The releasable cover sheet 42 is then applied to the device housing 28 at the nose end thereof (Page 10, lines 16-18).

In use of the injector device 10 with the infusion set 14, the cover sheet 42 is first removed and the injector device 10 is placed firmly against the patient's skin, with the infusion set 14 supported in the proper orientation and at a predetermined distance from the skin (Page 10, lines 20-23). A cap 94 shown in FIGS. 1-2, which prevents accidental projection of the infusion set 14 by preventing access to the trigger arms 38, is removed (Page 10, lines 23-25). Simple depression of the arms 38 releases the cocked plunger 30 for spring-loaded travel rapidly albeit with a controlled speed and force of insertion, to ensure penetration of the patient's skin with minimal discomfort, and in a manner which properly places the insertion needle and cannula 26 (Page 10, lines 25-28).

Following placement of the infusion set 14 the injector device with insertion needle 12 is withdrawn quickly and easily from the cannula (Page 10, lines 30-31). Thereafter, the injector device can be discarded and the infusion set 14 can be used in a normal manner to deliver a selected medication through the infusion tubing and

cannula 26 to the patient (Page 10, lines 31-34). As shown in FIG. 4, the safety cap 94 may conveniently be adapted to cooperate with an annular recess 33 formed in the head 32 of the plunger 30 for providing protection against the needle 12 (Page 10, line 34 – Page 11, line 2).

The removable cap 94 and cover sheet 42 allow the injector device 10 and the infusion set 14 mounted on the insertion needle 12 to be sterilized using a sterilizing gas that flows through the membrane formed by the cover sheet 42 (Page 11, lines 4-9).

An alternative embodiment of the invention is shown schematically in FIGS. 6-12 wherein an injector device assembly including a modified injector device 110 includes a generally cylindrical hollow device housing 128, a plunger 130 and a trigger-type actuator 134 formed integrally with the plunger 130 (Page 11, lines 23-26). As shown in FIG. 6, cover 194 covers the top of the injector device 110 and a further cover 142 covers the bottom end of the injector device 110 (Page 11, lines 26-27).

As shown in FIGS. 6-11, the plunger 130 has a generally cylindrical form with a head 132 and a central pin 129 including a metal insertion needle 112 secured thereto in a molding process (Page 11, lines 30-33). The pin 129 stops at a distance from a pair of outwardly turned legs 138' at the head 132, to accommodate for the infusion set 114 in the head 132 of the plunger 130 (Page 11,line 33 – Page 12, line 2). As shown in FIGS. 1-10, the insertion needle 112 extends through the infusion set 114 in a similar manner as described with reference to FIGS. 1-6 (Page 12, lines 2-3). As shown in FIGS. 6-7, an infusion set tubing 113 connected to the infusion set 114 is wound up in

the lower part of an annular space 115 between the device housing 128 and the plunger 130 (Page 12, lines 3-7).

As shown in FIG. 9, the device housing 128 again has a forward or nose end defining a flat and generally planar surface 125 (Page 12, lines 9-11). As shown in FIG. 6, the plunger 130 additionally includes a pair of resilient trigger arms 138 which are connected with the pair of outwardly turned legs 138' and which have out turned trigger fingers 158 at the sides thereof (Page 12, lines 11-13). The trigger arms 138 are adapted and sized for partial radial compression toward each other as they ride within the device housing when the plunger 130 is displaced from the advanced position (FIG. 6) to the retracted position (FIG. 9) (Page 12, lines 13-16). As the retracted position is reached, the trigger arms 138 are spring loaded by the resiliency to move first inwardly and then outwardly whereby the trigger fingers engage the upper surface of a shoulder 166 of the device housing 128 (Page 12, lines 17-20). In this position the trigger fingers 158 retain the plunger 130 in the retracted position (Page 12, lines 20-21).

As shown in FIGS. 6-7 and 12, a drive spring 136 is mounted within the device housing 128 to drive the plunger towards the nose of the device housing in the retracted position of the plunger 130, upon release of the trigger arms 138 (Page 12, lines 23-25).

Operation of the injector device assembly shown in FIGS. 6-12 is as follows. Since the injector device is preferably delivered to the patient in an uncocked state the plunger 130 must first be moved to the retracted position (Page 13, lines 11-14). To allow for retraction of the plunger 130, the upper cover 194, which spans across the

device housing 128, and the lower cover 142 are first removed, as shown in FIG. 7 (Page 13, lines 14-16). In this process, the infusion set 114 is exposed with the pointed end 112A of the insertion needle 112 projecting from the end of the soft flexible cannula 126 (Page 13, lines 17-19). The injector device 110 is then cocked by displacing the plunger 130 with respect to the device housing 128 as illustrated by the arrow in FIG. 9, until the fingers 158 engage the upper shoulder 166 of the device housing 120, indicating that the injector device is now ready for use (Page 13, lines 23-27). A release sheet 114' (FIG. 6) is then removed exposing an adhesive material on the bottom side of the infusion housing 114, and the patient or the nursing personnel then places the injector device on the patient's skin (Page 13, lines 27-30). The plunger 130 is released by application of an inwardly directed manual force on the arms 138 to transcutaneously place the insertion needle 112 and the cannula 126 (Page 13, lines 30-32). In an alternative embodiment, release of the plunger 130 may be caused by pressing manually on diametrically opposed outside areas of the device housing 128 to deform the housing 128 and thereby effect release of the trigger arms 138 (Page 13, line 32 – Page 14, line 2).

The injector device 110 is then removed, leaving the infusion set 114 on the patient's skin, illustrated by reference numeral 116, and the bottom cover 142 is then repositioned at the original place shown in FIG. 11 for protection of the insertion needle 112 which projects partially from the nose end of the device housing 128 (Page 14, lines 4-8).

The removable upper cover 194 and the bottom cover 142, when sealed to the device housing 128, allow the injector device 110 together with the infusion set 14 mounted on the insertion needle 112 to be sterilized in a conventional sterilization process, wherein one or both covers 142, 194 may include a permeable membrane allowing through-flow of the sterilizing agent (Page 14, lines 10-15).

FIGS. 13-16 show a third embodiment of the invention that includes an injector device 210 particularly suitable for the placement of a subcutaneous infusion set 214 at an acute angle relative to the skin of a patient (Page 14, lines 23-30). As best seen in FIG. 13, the injector device 210 has a device housing 228 with a flattened box like structure (Page 14, lines 32-34). As shown in FIGS. 14-16, the injector device 210 includes a plunger 230 mounted for longitudinal sliding movement within the box shaped housing between a rearward retracted position (FIG. 14) and a forward advanced position (FIG. 15) (Page 15, lines 13-15). The plunger 230 has a recessed head 232 (best seen in FIG. 16) at a forward end thereof shaped for receiving the housing of a subcutaneous infusion set 214 (Page 15, lines 18-20). Centrally in the recess, the head 232 is provided with a projecting metal insertion needle 212 securely connected thereto (Page 15, lines 20-22). A drive spring 236 positioned behind wall 280 reacts between a rearward face 264 of the plunger head 232 (Page 15, lines 25-27). The drive spring 236 normally biases the plunger 230 toward the advanced position (Page 15, lines 27-28). The front end of the plunger 230 has a trigger button 258 cooperating with the wall 224 of the device housing 28 (Page 15, lines 28-29). In

the retracted state of the plunger shown in FIG. 14, the trigger button 258 extends through an opening 222 formed in the upper wall 224 of the device housing 228 and aligned for reception of a release tab 220 on the wall 219' (Page 15, lines 29-33).

The trigger button 258 may be adapted for fingertip depression to release the plunger 230 for spring-loaded travel toward the advanced position, and for corresponding transcutaneous placement of the insertion needle 212, and of the cannula 226 travelling therewith, through the patient's skin (Page 16, lines 1-4).

Before opening the device housing 210, the assembly is maintained under sterile conditions (Page 16, lines 10-12). A removable cover sheet 294 (FIG. 13) is sealed to wall 224 to cover opening 222 (Page 16, lines 12-13). All other walls defining the closed housing 210 being sealed together, the cover sheet 294, when being permeable allows the injector device 210 together with the infusion set 214 mounted on the insertion needle 212 to be sterilized in a conventional sterilization process using a gas, wherein the sterilizing agent flows through the permeable membrane of the sheet 294 (Page 16, lines 13-18).

FIGS. 17, 23a and 23b show an example of an infusion set 14 suitable for use with the injector device according to the invention. The infusion set 14 includes a housing 3 with an internal chamber (not shown) (Page 16, lines 21-22). The infusion set 14 has a protruding soft and flexible cannula 26, which communicates with the internal chamber (Page 16, lines 28-29).

FIG. 18 shows how priming of the infusion set may be carried out prior to the placement of the infusion set using an injector device with a plunger shown only in part and carrying a hollow insertion needle 12, 112 having a lateral opening 12B, 112B (Page 17, lines 1-4). The medical insertion needle 12, 112 of the injector device extends into the internal chamber 2 of the infusion set 14 and through the cannula 26, 126, when the infusion set 14 is mounted in position on the injector device (Page 17, lines 4-7).

FIGS. 19-21e show a presently preferred embodiment of the injector device assembly that includes an injector device 310 that includes respective removable covers 342, 394, the cover 342 having a hollow for accommodating a part of the insertion needle 312 when the cover 342 is secured to the housing 328 (Page 17, lines 13-19). A spring is used for advancing the plunger 330 to the advanced position (Page 17, lines 20-22). An insertion needle 312 is preferably secured in a stable manner to the plunger 330 of the injection device (Page 17, lines 25-26). The plunger 330 and the drive may conveniently be formed integrally as a single component in a molding process (Page 17, lines 28-30).

The housing 328 is flexible in the sense that the application of a manual force against diametrically opposed depressions 303 will give rise to a slight deformation of the housing 328 for bringing about a release of the plunger in the retracted position and cause a spring loaded movement of the plunger 330 towards the advanced position (Page 17, line 32 – Page 18, line 3). For maintaining the plunger 330 in the retracted

position the housing 328 is provided with two opposed ledges 366 (Page 18, lines 3-5). Moreover, the housing 328 is provided with opposed dovetail projections 301 extending along the same general direction as the insertion needle 312 and adapted to connect with complementary recesses in the aforementioned spring, to secure the spring in relation to the housing 328 (Page 18, lines 5-9).

The plunger 330 generally includes a head 332, a hub 331 and, opposite the head 332, an enlarged gripping portion 331' which allows a user to manually pull the plunger 330 to a retracted position (Page 18, lines 11-13). The head 332 has a recess 332' for accommodating the infusion set 326 with cannula 326 through which the insertion needle 312 extends (Page 18, lines 16-18).

The drive which acts to drive the plunger 330 from the retracted position towards the advanced position when the fingers 358 are disengaged includes a spring (Page 19, lines 6-8). The spring would normally allow the plunger to be retracted several times, and provide the required force for subsequently advancing the plunger 330 (Page 20, lines 23-25).

FIG. 24 shows a variation of the injector device assembly of FIGS. 19-21 wherein a glucose sensor is included.

2. <u>Summary of Independent Claims</u>

With the above summary in mind, claim 50 claims an embodiment of the invention as an injector device assembly, the assembly including a sterile insertion set with a housing and a hollow cannula. Examples of the sterile insertion set are the

sterile insertion sets 14, 114, 314 of FIGS. 1-12, 17-19 and 23a-b that include a housing and a hollow cannula 26, 126, 326 (Page 7, lines 9-11, 16-19, Page 11, line 33 - Page 12, line 7 and Page 18, lines 16-20). The invention of claim 50 further recites a device housing wherein the insertion set is positioned removably from and within the device housing. Examples of the device housing are the device housings 28, 128, 328 of FIGS. 1-12, 19 and 24 in which insertion sets are removably positioned therein (Page 7, lines 2-7 and 22-25, Page 10, lines 31-34, Page 11, lines 23-26, Page 14, lines 4-8, Page 17, lines 17-20). The invention of claim 50 further recites a plunger received within the device housing for movement between an advanced position and a retracted position, the cannula being transcutaneously placed upon movement of the plunger from the retracted position to the advanced position, the insertion set being separable from the plunger. Examples of the plungers are the plunger 30, 130, 330 of FIGS. 1-12, 19 and 24 received within the device housing 28, 128, 328 and movable between an advanced position and retracted position, the cannula of the insertion set being transcutaneously placed in the advanced position and the infusion set being separable from the plunger (Page 7, lines 2-6, Page 12, lines 13-16, Page 17, line 32-Page 18, line 3). The invention of claim 50 further recites that the device housing has a forward end defining a surface of placement against the skin of a patient. Examples of the forward end are the ends of device housings 28, 128, 328 of FIGS. 1-12, 19 and 24 that include cover sheets 42, 142, 342 and/or release sheets 14', 114' (Page 9, lines 16-18, Page 10, lines 20-23, Page 13, lines 27-30, Page 17, lines 17-20). The invention of

claim 50 further recites a cover member covering an opening defined in the forward end and removably connected to a portion of the device housing, the cover member and the device housing assuring sterile conditions of the insertion set within the device housing prior to removal of the cover member. Examples of the recited cover member are the cap 94, 194, 394 and the cover sheets 42, 142, 342 of FIGS. 1-12, 19 and 24 (Page 11, lines 4-9, and lines 26-28, Page 14, lines 10-15, and Page 17, lines 17-20).

Claim 72 claims an embodiment of the invention as an injector device assembly, the assembly including a sterile insertion set with a housing and a hollow cannula, a molded device housing; the insertion set is positioned within the device housing for delivery of the sterile insertion set to a patient. Examples of the sterile insertion set are the sterile insertion sets 14, 114, 314 of FIGS. 1-12, 17-19 and 23a-b that include a housing and a hollow cannula 26, 126, 326 (Page 7, lines 9-11, 16-19, Page 11, line 33 - Page 12, line 7 and Page 18, lines 16-20). An example of the molded device housing that contains the insertion set is the device housing 28 of FIGS. 1-5 in which an insertion set is removably positioned therein (Page 7, lines 2-7 and 22-25, Page 10, lines 31-34). Additional examples of a molded device housing are the device housings 128, 228, 328 shown in FIGS. 6, 13 and 19 (Page 11, lines 23-26, page 14, line 33, page 17, line 32-page 18, line 3). The invention of claim 72 further recites a molded plunger received within the device housing for movement between an advanced position and a retracted position, the cannula being transcutaneously placed upon movement of the plunger from the retracted position to the advanced position, the

insertion set being separable from the plunger. An example of the plunger is the plunger 30 of FIGS. 1-5 received within the device housing 28 and movable between an advanced position and retracted position, the cannula of the insertion set being transcutaneously placed in the advanced position and the infusion set being separable from the plunger (Page 7, lines 2-6). Additional examples of the plunger include the plungers 130, 230, 330 shown in FIGS. 6, 14 and 19 (Page 11, lines 23-26, page 15, lines13-15, page 17, lines 28-30). The invention of claim 72 further recites a lock for releasably locking the plunger in the retracted position, the housing being manually deformable to effect release of the plunger. An example of the recited lock is shoulder 66 when engaged with trigger fingers 58 (Page 10, lines 5-7). Another example of a lock is shown in FIGS. 19 and 20d where the ledge 366 is releasably locked in engagement with finger 358 (Page 18, lines 24-27). Examples of the deformable device housing include device housing 28, 128, 328 that is pressed manually on opposed outside areas (Page 9, lines 4-7, Page 13, line 32-Page 14, line 2, Page 17, line 32-Page 18, line 3). The invention of claim 72 further recites a spring for urging the plunger from the retracted position towards the advanced position, the insertion set being separable from the plunger after placement of the cannula. An example of the recited spring is drive spring 36, 136, 236 of FIGS. 1-2, 6-7 and 14-16 (Page 10, lines 7-11, page 12, lines 23-28, page 15, lines 25-28). An example of a separable insertion set is the infusion set 14 that stays on the patient after the injector device is removed and discarded (Page 10, lines 30-34). The invention of claim 72 includes the device

housing having a forward end defining a surface of placement against the skin of a patient with the device housing in a predetermined orientation relative to the patient's skin. An example of the forward end is the end of device housing 28 of FIGS. 1-5 that includes cover sheet 42 and/or release sheet 14' (Page 9, lines 16-18, Page 10, lines 20-23). The invention of claim 72 further recites a removable cover member covering an opening defined in the forward end and connected to a portion of the device housing, the cover member and the device housing assuring sterile conditions of the insertion set within the device housing prior to removal of the cover member. Examples of the recited cover member are cap 94 and the cover sheet 42 of FIG. 1-5 (Page 11, lines 4-9). Additional examples of the cover member include the covers 142, 194, and 342, 394 shown in FIGS. 6 and 19 (Page 11, lines 26-28, page 17, lines 17-20).

Claim 90 claims an embodiment of the invention as a mode of making an injector device assembly wherein the method includes providing an injector device housing, the injector device housing having a movable plunger and providing an insertion set, the insertion set having an insertion set housing and a hollow cannula. The invention of claim 90 recites placing the insertion set within the injector device housing. Examples of the sterile insertion set are the sterile insertion sets 14, 114, 214, 314 of FIGS. 1-16, 19, 23a-24 that include a housing and a hollow cannula 26, 126, 226, 326 (Page 7, lines 9-11 and 16-19, Page 11, line 33 - Page 12, line7, Page 15, lines 18-20, Page 16, lines 28-29, Page 18, lines 16-20). Examples of the movable plungers are the plungers 30, 130, 230, 330 of FIGS. 1-15, 19 and 24 received within the device housing 28, 128,

228, 328 and movable between an advanced position and retracted position, the cannula of the insertion set being transcutaneously placed in the advanced position and the infusion set being separable from the plunger (Page 7, lines 2-6, Page 12, lines 13-16, Page 15, lines 18-20, Page 17, line 32-Page 18, line 3). The invention of claim 90 further includes connecting at least one releasable cover to at least a portion of the injector device housing to seal the insertion set within the injector device housing, the cover including a membrane. Examples of the recited releasable cover are cap 94 and cover sheets 42, 142, 294 of FIGS. 1-15 and 24 (Page 11, lines 4-9, Page 14, lines 10-15, Page 16, lines 13-18). Additionally removable covers 342, 394 are shown in FIG. 19 (Page 17, lines 17-25.) The invention of claim 90 further includes sterilizing the insertion set by flowing a sterilizing agent through the membrane into an interior of the injector device housing. Examples of the recited sterilizing by flowing a sterilizing agent through a membrane is described at Page 11, lines 4-9, Page 14, lines 10-15 and Page 16, lines 13-18 of Appellants' Specification.

Claim 93 claims an embodiment of the invention as an injector device, the device including a generally cylindrically shaped housing having a cavity formed therein, the housing including a forward end, the forward end defining a generally planar surface for placement against the skin of the patient. An example of the recited housing is the device housing 28 of FIGS. 1-5 that has an end that is placed on the patient (Page 7, lines 2-7). Additional examples of a device housing are the device housings 128, 228, 328 shown in FIGS. 6, 13 and 19. (Page 11, lines 23-26, page 14, line 33, page 17, line

32-page 18, line 3). An example of the forward end is the end of device housing 28 of FIGS. 1-5 that includes cover sheet 42 and/or release sheet 14' (Page 9, lines 16-18, Page 10, lines 20-23). The forward end of the device housing 128 including a generally planar surface 125 is shown in FIG. 9 (Page 12, lines 9-11.) The invention of claim 93 further recites a carrier member adapted for at least partial reception in the cavity, the carrier member including at least one piercing member substantially non-detachably secured to the carrier member. An example of the carrier member is the plunger 30 of FIGS. 1-5 received within the device housing 28 and movable between an advanced position and retracted position, the plunger having a needle 12 (Page 7, lines 1-6). Additional examples of the carrier member include the plungers 130, 230, 330 shown in FIGS. 6, 14 and 19 (Page 11, lines 23-26, page 15, lines13-15, page 17, lines 28-30). The invention of claim 93 further recites a drive for urging movement of the carrier member relative to the housing, the drive extending at least partially around at least a portion of the carrier member. Examples of the drive include spring 36 which extends around the trigger arms 38 of the plunger 30 as shown in FIGS. 1-2 (Page 8, line 32 – Page 9, line 4) and drives 36, 136, 236 of FIGS. 1-2, 6-7 and 14-16 (Page 10, lines 7-11, page 12, lines 23-28, page 15, lines 25-28). The invention of claim 93 further includes a releasable cover member covering the forward end, the cover member including an upstanding portion defining a bore. An example of the releasable cover member is cap 94 as shown in FIG. 4 (Page 10, line 34- Page 11, line 2). Additional examples of the cover member include the covers 142, 194, and 342, 394 shown in

FIGS. 6 and 19 (Page 11, lines 26-28, page 17, lines 17-20). The invention of claim 93 further involves having the at least one piercing member adapted to receive the removable medical device. An example of such a piercing member is shown in FIGS. 1-2, wherein needle 12 passes through the infusion set 14. Additional examples of the piercing member include needles 112, 212, 312, shown in FIGS. 6, 11, 16, 18 and 19.

Claim 97 claims an embodiment of the invention as an injector device, the injector device including a sterile insertion set with a housing and a hollow cannula. Examples of the sterile insertion set are the sterile insertion sets 14, 114, of FIGS. 1-12, 23a-24 that include a housing and a hollow cannula 26, 126 (Page 7, lines 9-11 and 16-19, Page 11, line 33 - Page 12, line 7). Additional examples of the infusion set are the infusion sets 214, 314 shown in FIGS. 14-16 and 19 (Page 14, lines 28-30 and page 18, lines 18-20). The invention of claim 97 further recites a device housing having a cavity formed therein, wherein the insertion set is positioned removably from and within the device housing. Examples of the device housing are the device housings 28, 128 of FIGS. 1-12 and 24 in which insertion sets are removably positioned therein (Page 7, lines 2-7 and 22-25, Page 10, lines 31-34, Page 11, lines 23-26, Page 14, lines 4-8). Additional examples of a device housing are the device housings 128, 228, 328 shown in FIGS. 6, 13 and 19. (Page 11, lines 23-26, page 14, line 33, page 17, line 32-page 18, line 3). The invention of claim 97 further recites a plunger having a piercing member connected to the plunger and positioned at least partially within the cavity, the piercing member extending at least partially through the cannula of the insertion set and the

piercing member configured to move the insertion set toward the skin of a patient. Examples of the plungers are the plunger 30, 130, 230, 330 of FIGS. 1-12, 14 and 19 received within the device housing 28, 128, 228, 328 and movable between an advanced position and retracted position, wherein the plungers include a needle 12, 112, 212, 312 (Page 7, lines 2-6, Page 8, lines 20-21, Page 11, lines 30-33, Page 12, lines 13-16, Page 15, lines 20-21, Page 17, lines 25-26). The invention of claim 97 further recites that the device housing has a forward end defining a surface of placement against the skin of a patient. Examples of the forward end are the ends of device housings 28, 128 of FIGS. 1-12 that include cover sheets 42, 142, 342 and/or release sheets 14', 114' (Page 9, lines 16-18, Page 10, lines 20-23, Page 13, lines 27-30). The invention of claim 97 further recites a cover removably connected to a portion of the device housing, the cover accommodating a part of the piercing member, the cover and the device housing assuring sterile conditions of the insertion set within the device housing prior to removal of the cover. Examples of the recited cover are the cap 94 and the cover sheets 42, 142 of FIGS. 1-12 (Page 11, lines 4-9, Page 14, lines 10-15). Additional examples of the cover member include the covers 142, 194, and 342, 394 shown in FIGS. 6 and 19 (Page 11, lines 26-28, page 17, lines 17-20).

Claim 100 claims an embodiment of the invention as a mode of providing an injector device assembly wherein the method includes providing an injector device housing, the injector device housing having a movable plunger and a piercing member connected to the plunger. The invention of claim 100 recites providing an insertion set,

the insertion set having an insertion set housing and a hollow cannula. The invention of claim 100 recites placing the insertion set within the injector device housing so that the piercing member extends at least partially through the cannula. Examples of the sterile insertion set are the sterile insertion sets 14, 114, 214, 314 of FIGS. 1-16, 19, 23a-24 that include a housing and a hollow cannula 26, 126, 226, 326 (Page 7, lines 9-11 and 16-19, Page 11, line 33 - Page 12, line7, Page 15, lines 18-20, Page 16, lines 28-29, Page 18, lines 16-20). Examples of the movable plunger are the plungers 30, 130, 230, 330 of FIGS. 1-15 and 19 received within the device housing 28, 128, 228, 328 and movable between an advanced position and retracted position, the cannula of the insertion set being transcutaneously placed in the advanced position and the infusion set being separable from the plunger (Page 7, lines 2-6, Page 12, lines 13-16, Page 15, lines 18-20, Page 17, line 32-Page 18, line 5). The plungers 30, 130, 230, 330 have needles 12, 112, 212, 312 (Page 7, lines 1-2, Page 11, lines 30-33, Page 15, lines 20-22, Page 17, line 25-26). The invention of claim 100 further includes placing the insertion set within the injector device so that the piercing member extends at least partially through the cannula. Examples of such an insertion set are infusion sets 14, 114, 214, 314 and the needles 12, 112, 212, 312 that extend through the sets and cannulas 26, 126, 226, 326 as shown in FIGS. 1-2, 6-11, 16 and 19. The invention of claim 100 further includes connecting at least one removable cover to a portion of the injector device housing to cover an opening defined in the injector device housing and to seal the insertion set within the injector device housing, the cover accommodating a

part of the piercing member. Examples of the recited removable cover are cap 94 and cover sheets 42, 142, 294, 342, 394 of FIGS. 1-15 and 19 (Page 11, lines 4-9, Page 14, lines 10-15, Page 16, lines 13-18, Page 17, lines 17-20). The invention of claim 100 further includes sterilizing the insertion set within the injector device housing. Examples of the recited sterilizing are described at Page 11, lines 4-9, Page 14, lines 10-15 and Page 16, lines 13-18 of Appellants' Specification.

Regarding only independent claims 50, 72, 90, 93, 97 and 100 and dependent claims 58, 65, 67, 71, 78, 82-85, 88, 89 and 94-96, which are argued separately below in Section VII, there are no means-plus-function terms or step-plus-function terms present therein. This statement is not to be construed as an admission whether or not the remaining claims contain means-plus-function terms or step-plus-function terms.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There are four grounds of rejection presented for review:

1) the rejection of claims 50, 56, 67, 69-72, 78, 80-88 and 90-96 under 35 U.S.C. § 102(b) as being anticipated by Miskinyar, U.S. Patent No. 5,527,287;

2) the rejection of claims 93-96 under 35 U.S.C. § 102(e) as being anticipated by Safabash et al., U.S. Patent No. 6,293,925;

3) the rejection of claim 58 under 35 U.S.C. § 103 as being obvious in view of Miskinyar and Teeple, Jr., U.S. Patent No. 5,807,316; and

4) the rejection of claims 50-59, 65-72 and 78-100 under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar.

VII. ARGUMENT

A. 35 U.S.C. § 102

1. Miskinyar

a. Claims 50, 56, 67 and 69-71

Claims 50, 56, 67 and 69-71 were rejected in the Office Action of April 22, 2009 (hereinafter "the Office Action") under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, independent claim 50 recites "a sterile insertion set with a housing and a hollow cannula," "said insertion set positioned removably from and within said housing" and "said insertion set being separable from said plunger." The Examiner at page 3 of the Office Action has asserted that Miskinyar discloses a sterile insertion set with a housing corresponding to item 74 and a cannula corresponding to item 22. The rejection is improper for the reason that Miskinyar fails to disclose having an "insertion set being separable from said plunger" as recited in claim 50. Indeed, the Examiner at page 3 of the Office Action fails to recite one portion of Miskinyar that discloses having ampoule 74 and hypodermic needle 22 being separable from ampoule member 18. It is noted that the Examiner has taken the position at page 5 of the Office Action that the term "infusion set" has been given no special definition in the specification and so could mean a needle, "a pump, an IV bag, essentially anything with a fluid conduit for subcutaneous fluid delivery." Appellants

traverse such an interpretation on several fronts. First, Appellants' Specification at page 7, lines 9-25, states that an infusion set is used to infuse medical fluids to a patient and generally includes a housing with an internal chamber and a cannula 26 which communicates with the internal chamber. Based on Appellants' Specification one of ordinary skill would not interpret an infusion set in the same manner as the Examiner. The Examiner's interpretation is improper for the additional reason that the Examiner ignores the language of the claims. For example, claim 50 specifically recites that the sterile insertion set includes "a housing and a hollow cannula." A pump, an IV bag and many items with a fluid conduit for subcutaneous fluid delivery do not include a cannula. Accordingly, the Examiner's interpretation of "insertion set" has no merit.

Suppose for argument's sake only that Miskinyar's hypodermic needle 22 could be deemed an insertion set by itself, the fact remains that claim 50 requires that the insertion set is "separable from said plunger." Miskinyar discloses that hypodermic needle 22 is attached to ampoule member 18 since it moves with member 18 from the loaded position shown in FIG. 2 to the released position of FIG. 3. It is noted that in the Advisory Action mailed on July 31, 2008 the Examiner asserted that Miskinyar's hypodermic needle 22 was intended to be cut from the housing and so was separable in the manner recited in claim 50. If that is the Examiner's position in the Office Action, then Miskinyar does not disclose that its needle is intended to be cut from the member 18. Does cutting off a needle and leaving the needle in a patient's skin while the remainder of the device is removed sound like a good idea? Obviously not. While in

general it might be acceptable practice in the medical field to use a needle to penetrate epidermis to inoculate a patient, inserting a needle, cutting it off, and leaving it in the patient as proposed by the Examiner would not be safe, sanitary, or intended.

As mentioned above, claim 50's insertion set includes a housing. The Examiner at page 3 of the Office Action has asserted that ampoule 74 is a housing of an insertion set. Assuming for argument's sake only that ampoule 74 is a housing, it is not separable from ampoule member 18. Indeed, ampoule 74 is sealed to (i.e., not removable or releasable from) the inner walls of the ampoule chamber 24:

> Thus the needle 22 is extended before air pressure is applied to the ampoule 74 contained within the ampoule chamber 24. The ampoule 74 is formed by an elastic balloon which is received within and sealed to the inner walls of the ampoule chamber, containing medication 78 within its sealed interior. (Miskinyar Col. 3, lines 59–64, emphasis supplied).

Since both hypodermic needle 22 and ampoule 74 are not separable from ampoule member 18, Miskinyar does not disclose an infusion set that is separable from a plunger as recited in claim 50. Accordingly, the rejection is improper and should be reversed.

Claims 56, 67 and 69-71 depend directly or indirectly on claim 50 and so their rejections should be reversed for the reasons given above with respect to claim 50.

b. Claim 71

Claim 71 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 71 depends indirectly on claim 50 and so is not anticipated for the reasons given above at

pages 25-27 in Section VII.A.1.a. with respect to claim 50. The claim is not anticipated for the additional reason that Miskinyar does not disclose a releasable cover that allows "through-flow of a sterilizing agent into said device housing with said insertion set." The Examiner at page 3 of the Office Action has implied that sterile tape 72 allows for the recited through-flow but does not identify where Miskinyar discloses that tape 72 has the recited through-flow property. A review of Miskinyar reveals that there is no disclosure of having tape 72 with a through-flow property. Without such disclosure, claim 71 is not anticipated by Miskinyar and so the rejection is improper and should be reversed.

c. Claims 72, 78, 80, 81, 86 and 87

Claims 72, 78, 80, 81, 86 and 87 were rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, independent claim 72 recites "a sterile insertion set with a housing and a hollow cannula" and "said insertion set being separable from said plunger." This is the same language used in claim 50 and so the recited "sterile insertion set with a housing and a hollow cannula" of claim 72 is not anticipated by Miskinyar for the same reasons given above at pages 25-27 in Section VII.A.1.a.

Claim 72 is not anticipated by Miskinyar for the additional reason that Miskinyar fails to disclose a device housing that is "manually deformable to effect release of said plunger." The Examiner at pages 5 and 6 of the Office Action has asserted that button 33 is part of housing 10. Assuming for argument's sake only that the button 33 can be

considered part of housing 10, the fact remains that Miskinyar does not disclose that button 33 is deformable. A review of Appellants' Specification regarding the embodiment of FIGS. 1-5 reveals that:

> [R]elease of the plunger 30 may be caused by pressing manually on diametrically opposed outside areas of the device housing 28 to deform the housing 28 and thereby effect release of the trigger arms 38. (P. 9, lines 5-7).

A similar statement is made at page 13, line 32 to Page 14, line 2 regarding the embodiment of FIGS. 6-12. In each embodiment, a user presses against the housing 28, 128 so that the shape of housing changes to such an extent that the housing contacts the trigger arms 38, 138 resulting in the release of the plunger 30, 130. Thus, "deform," as understood by one of ordinary skill reviewing Appellants' Specification, means that the shape of an object will be changed. This meaning is in agreement with the definition of "deform" which is "to alter the shape of by stress" according to Webster's Ninth New Collegiate Dictionary. With the above meaning of "deform" in mind, Miskinyar does not disclose deforming button 33. While Miskinyar does disclose changing the position of button 33, Miskinyar does not disclose altering the shape/deforming button 33. Accordingly, Miskinyar does not anticipate claim 72 and so the rejection should be reversed.

Claims 78, 80, 81, 86 and 87 depend directly or indirectly on claim 72 and so their rejections should be reversed for the reasons given above with respect to claim 72.

d. Claim 82

Claim 82 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 82 depends directly on claim 72 and so is not anticipated for the reasons given above at pages 28-29 in Section VII.A.1.c. with respect to claim 72. The claim is not anticipated for the additional reason that Miskinyar does not disclose manual engagement areas for manual deformation of the device housing. As mentioned previously in Section VII.A.1.c.; button 33 of Miskinyar is not deformable and so it follows that Miskinyar does not disclose the recited manual engagement areas. Without such disclosure, claim 82 is not anticipated by Miskinyar and so the rejection is improper and should be reversed.

e. Claim 83

Claim 83 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 83 depends directly on claim 82 and so is not anticipated for the reasons given above at page 30 in Section VII.A.1.d. with respect to claim 82. The claim is not anticipated for the additional reason that Miskinyar does not disclose manual engagement areas for manual deformation of the device housing that are diametrically opposed on the device housing and peripherally offset with respect to the lock. As mentioned previously in Section VII.A.1.c; button 33 of Miskinyar is not deformable and so it follows that Miskinyar does not disclose the recited manual engagement areas. Without such

disclosure, claim 83 is not anticipated by Miskinyar and so the rejection is improper and should be reversed.

f. Claim 84

Claim 84 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 84 depends directly on claim 83 and so is not anticipated for the reasons given above at pages 30-31 in Section VII.A.1.e. with respect to claim 83. The claim is not anticipated for the additional reason that Miskinyar does not disclose manual engagement areas for manual deformation of the device housing that are diametrically opposed on the device housing and peripherally offset about 90° with respect to the lock. As mentioned previously in Section VII.A.1.c, button 33 of Miskinyar is not deformable and so it follows that Miskinyar does not disclose the recited manual engagement areas. Without such disclosure, claim 83 is not anticipated by Miskinyar and so the rejection is improper and should be reversed.

g. Claim 85

Claim 85 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 85 depends directly on claim 83 and so is not anticipated for the reasons given above at pages 30-31 in Section VII.A.1.e. with respect to claim 83. The claim is not anticipated for the additional reason that Miskinyar does not disclose fingertip size manual engagement areas for manual deformation of the device housing that are diametrically

opposed on the device housing and peripherally offset with respect to the lock. As mentioned previously in Section VII.A.1.c; button 33 of Miskinyar is not deformable and so it follows that Miskinyar does not disclose the recited manual engagement areas. Without such disclosure, claim 85 is not anticipated by Miskinyar and so the rejection is improper and should be reversed.

h. Claim 88

Claim 88 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 88 depends indirectly on claim 72 and so is not anticipated for the reasons given above at pages 28-29 in Section VII.A.1.c. with respect to claim 72. The claim is not anticipated for the additional reason that Miskinyar does not disclose a releasable cover that allows "through-flow of a sterilizing agent into said device housing with said insertion set." The Examiner at page 3 of the Office Action has implied that sterile tape 72 allows for the recited through-flow but does not identify where Miskinyar discloses that tape 72 has the recited through-flow property. A review of Miskinyar reveals that there is no disclosure of having tape 72 with a through-flow property. Without such disclosure, claim 88 is not anticipated by Miskinyar and so the rejection is improper and should be reversed.

i. Claims 90-92

Claims 90-92 were rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular,

independent claim 90 recites "sterilizing said insertion set by flowing a sterilizing agent through said membrane into an interior of said injector device housing" as recited in claim 90. Miskinyar does not disclose such sterilization. It is noted that the Examiner does not refer to this limitation and does not recite any portion of Miskinyar as disclosing the flowing of a sterilizing agent. Accordingly, the rejection is improper and should be withdrawn.

Claims 91 and 92 depend directly on claim 90 and so their rejections should be reversed for the reasons given above with respect to claim 90.

j. Claim 93

Claim 93 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. For example, the Examiner has not performed any analysis regarding claim 93 and so unfairly leaves it to Appellants to guess the reasons behind the rejection. With that said, independent claim 93 recites "a releasable cover member covering said forward end, said cover member comprising an upstanding portion defining a bore" wherein the forward end defines "a generally planar surface for placement against the skin of the patient." Assuming the Examiner is relying on tape 80 as a cover, the tape does not have an upstanding portion defining a bore as recited in claim 93. Accordingly, claim 93 is not anticipated by Miskinyar and so the rejection is improper and should be reversed.

k. Claim 94

Claim 94 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 94 depends directly on claim 93 and so is not anticipated for the reasons given above at page 33 in Section VII.A.1.j. with respect to claim 93. The claim is not anticipated for the additional reason that Miskinyar does not disclose an upstanding portion of a cover member that surrounds a portion of a needle. As mentioned previously in Section VII.A.1.j., Miskinyar's tape 80 does not have an upstanding portion that defines a bore and so it follows that Miskinyar does not disclose the recited upstanding portion. Without such disclosure, claim 94 is not anticipated by Miskinyar and so the rejection is improper and should be reversed.

l. Claim 95

Claim 95 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 95 depends directly on claim 93 and so is not anticipated for the reasons given above at page 33 in Section VII.A.1.j. with respect to claim 93. The claim is not anticipated for the additional reason that Miskinyar does not disclose an upstanding portion of a cover member that is cylindrically shaped. As mentioned previously in Section VII.A.1.j., Miskinyar's tape 80 does not have an upstanding portion that defines a bore and so it follows that Miskinyar does not disclose the recited cylindrically shaped upstanding

portion. Without such disclosure, claim 95 is not anticipated by Miskinyar and so the rejection is improper and should be reversed.

m. Claim 96

Claim 96 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Miskinyar. Appellants traverse the rejection. In particular, claim 96 depends directly on claim 93 and so is not anticipated for the reasons given above at page 33 in Section VII.A.1.j. with respect to claim 93. The claim is not anticipated for the additional reason that Miskinyar does not disclose tape 80 and housing 10 being "configured to provide sterile conditions for the medical device prior to removal of said cover member." Miskinyar is silent regarding generating sterile conditions for a medical device and so the claim is not anticipated. The rejection is improper and should be reversed.

2. Safabash et al.

a. Claims 93-95

Claims 93-95 were rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by Safabash et al. Appellants traverse the rejection. In particular, independent claim 93 recites "a releasable cover member covering said forward end, said cover member comprising an upstanding portion defining a bore" wherein the forward end defines "a generally planar surface for placement against the skin of the patient." At page 3 of the Office Action, the Examiner relies on piercing member guard 414 and adhesive backing 416 as corresponding to the recited cover member. Such

reliance is incorrect. As shown in FIG. 40c, guard 414 is placed over piercing member 402 to move the carrier body 504 to a retracted position (Col. 19, lines 35-42). As shown in FIG. 40d, the guard 414 is later removed. As can be seen in FIG. 40d, the insertion device 500 has a C-shaped bottom edge. As shown in FIGS. 40e-f, the C-shaped bottom edge is placed on a surface during installation of insertion set 400 (Col. 19, lines 46-55). Safabash et al. shows both the adhesive backing 416 and the needle guard 414 are seated inside the barrel 502 of the insertion device 500 and do not removably connect to a front end portion of the housing. Safabash et al. is silent, however, as to how the needle guard 414 and the adhesive backing are releasably connected to the device housing as recited in independent claim 93. Indeed, the teachings in Safabash et al. undermine the very reason being proffered by the Examiner as to why the adhesive backing 416 and the needle guard 414 do not releasably connect to a forward end of the device housing. As taught by Safabash et al., a "user presses against the piercing member guard 414 (or needle guard) to seat the piercing member hub (or needle hub) and the insertion set 400 *in the cavity* of the carrier body 504." (Safabash, et al. Col. 19, lines 27–30 (emphasis added); see also Figs 40a–40d.) Therefore, the needle guard 414 and the adhesive backing 416 are prevented from covering the "barrel 502 (or device housing) having a surface seat 501." (Safabash et al., Col. 15, line 67 through Col. 16, line 1.) Accordingly, Safabash et al. does not anticipate claim 93 and so the rejection should be reversed.

Claims 94 and 95 depend directly on claim 93 and so their rejections should be reversed for the reasons given above with respect to claim 93.

b. Claim 96

Claim 96 was rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by Safabash et al. Appellants traverse the rejection. In particular, claim 96 depends directly on claim 93 and so is not anticipated for the reasons given above at pages 35-36 in Section VII.A.2.a. with respect to claim 93. The claim is not anticipated for the additional reason that Safabash et al. does not disclose guard 414 and device 500 being "configured to provide sterile conditions for the medical device prior to removal of said cover member." Indeed, reference to sterilization appears only once in Safabash et al. and that appearance in no way relates to an insertion set: "The user first cleans and sterilizes an insertion site on the skin." (Safabash et al., Col. 19, lines 18–19.) Further, it is clear from Figures 31 and 32 of Safabash et al. that the insertion set is handled by the user to put the insertion set into the open end of the non-sterile housing. It is clear that the device of Safabash et al. is not necessarily sterile when mounted in the Safabash et al. injector, in the open air. In addition, the Safabash et al. injector includes multiple parts that are pieced together as well as slots 52 and cutouts 40 along the side of the barrel 28 to accommodate infusion tubing 22 and wings 24 on the insertion set 14 that extend outward from the barrel 28 (Col. 9, lines 30-44 and 52-59). One could not simply add covers 38 and 72 of Miskinyar to each end of Safabash and assure sterile conditions of the insertion set within the housing of Safabash due to

the open design caused by the slots and cutouts. In addition, simply adding the covers of Miskinyar to each end of Safabash does not address how the tubing and wings extending out from the Safabash device would be covered or kept sterile.

As a result, the insertion set cannot be sterile once it is placed within the housing of Safabash et al. Accordingly, the rejection is improper and should be reversed.

B. 35 U.S.C. § 103

1. Miskinyar and Teeple, Jr.

Claim 58 was rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Miskinyar and Teeple, Jr. Appellants traverse the rejection. In particular, claim 58 depends directly on independent claim 50. As mentioned above in Section VII.A.1.a; Miskinyar fails to disclose "a sterile insertion set with a housing and a hollow cannula" wherein the insertion set is "separable from said plunger." There is no reason in Teeple, Jr. or otherwise to alter Miskinyar's needle 22 and ampoule 74 to be separable from ampoule member 18. In fact, Teeple Jr. is directed to the mixing and delivery of anesthesia and not to an injector or an insertion set.

The rejection is improper for the additional reason that both Miskinyar and Teeple, Jr. do not disclose the recited indicia. The Examiner admits Miskinyar does not teach the "indicia" but, with a broad brush, suggests that Teeple provides the missing element. However, the Examiner is taking Teeple out of context. That reference related to shelf life of anesthetic drugs that break down over time when stored in vials. See Teeple, col. 18, lines 19–28. Also, the Examiner's truncated reading of the claim limitation reads out of the claim the recited indicia on the "cover member, and wherein

the releasable cover member assures sterile conditions of the infusion set prior to releasing the cover member." The Examiner does not explain how the bar codes for tracking expired anesthetic drugs would assure "sterile conditions of the infusion set prior to releasing the cover member." This is not taught, described, or even remotely suggested by Teeple, Jr.

2. Safabash et al. and Miskinyar

a. Claims 50-57, 59, 66, 68-70, 72, 78-81, 86, 87, 97-99

Claims 50-57, 59, 66, 68-70, 72, 78-81, 86, 87 and 97-99 were rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar. Appellants traverse the rejection. In particular, independent claims 50, 72 and 97 recite a sterile insertion set that is separable from the plunger or a sterile insertion set that is positioned removably from and within the device housing. Claims 50, 72 and 97 further recite that the cover member and the device housing assure sterile conditions of the insertion set within the device prior to removal of the cover member. The Examiner at page 4 of the Office Action has conceded that Safabash et al. does not disclose a sterilized injector device. The Examiner relies on Miskinyar for overcoming the deficiencies of Safabash et al. The Examiner asserts that Miskinyar discloses using a sterile injector with front 72 and back 38 covers. The Examiner also asserts that Safabash et al. discloses a front cover 414, 416.

The rejection is improper for several reasons. First, the cover 414, 416 of Safabash et al. is not "configured to provide sterile conditions for the medical device

prior to removal of said cover member." Instead, guard 414 merely covers a piercing member 402. In addition, as discussed above in Section VII.A.2, Safabash et al. shows both the adhesive backing 416 and the needle guard 414 are seated inside the barrel 502 of the insertion device 500 and do not removably connect to a front end portion of the housing. The remainder of the end injector of Safabash et al. having the infusion set mounted therein is open to the air and thus cannot be assured of sterility prior to removal of the cover. Next, the Examiner reads the tape 72 of Miskinyar as a front "cover." This conclusion does not take proper account of the claim requirement that the cover must be removably connected to the housing. Miskinyar's "tape 72" cannot be considered a releasable housing cover of the claimed invention. Miskinyar actually teaches away from the claimed releasable housing cover: "tape 72 which is permanently bonded to the housing." (Col. 4, l. 2, emphasis added). In addition, the permanently bonded tape 72 does not permit any removably positioned device behind the tape 72 to be removable from the plunger. Further, even if the tape 72 and the cover 38 of Miskinyar could be combined with the injectors of Safabash et al, the injectors disclosed by Safabash et al. include multiple parts that are pieced together as well as slots and cutouts along the side of the barrel to accommodate infusion tubing and wings on the insertion set. One could not simply add covers to each end of Safabash et al. and assure sterile conditions of the insertion set within the housing. Thus, one skilled in the art would not be motivated to combine Safabash et al. and Miskinyar.

Accordingly, the rejection is improper and should be reversed.

Claims 51-57, 59, 66, 68-70, 78-81, 86, 87 and 98-99 depend directly or indirectly on claim 50, claim 72 or claim 97 and so their rejections should be reversed for the reasons given above with respect to claims 50, 72 and 97.

b. Claim 58

Claim 58 was rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar. Appellants traverse the rejection. In particular, claim 58 depends indirectly on claim 50 and so is not obvious for the reasons given above at pages 39-41 in Section VII.B.2.a. with respect to claim 50. The claim is not obvious for the additional reason that neither Safabash et al. nor Miskinyar discloses a cover member with indicia relating to shelf life of the assembly. Since there is no reason given by the Examiner, Safabash et al. or Miskinyar to use such a cover member, a *prima facie* case of obviousness has not been established and so the rejection is improper and should be reversed.

c. Claim 65

Claim 65 was rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar. Appellants traverse the rejection. In particular, claim 65 depends indirectly on claim 50 and so is not obvious for the reasons given above at pages 39-41 in Section VII.B.2.a. with respect to claim 50. The claim is not obvious for the additional reason that neither Safabash et al. nor Miskinyar discloses a cover member including a hollow for receiving a part of the insertion needle. The Examiner at page 4 of the Office Action has asserted that it would have been obvious to

use the tapes 72 and 80 of Miskinyar. However, such tapes do not include a hollow for receiving a part of the insertion needle. Since there is no reason given by the Examiner, Safabash et al. or Miskinyar to use the cover member recited in claim 65, a *prima facie* case of obviousness has not been established and so the rejection is improper and should be reversed.

d. Claim 67

Claim 67 was rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar. Appellants traverse the rejection. In particular, claim 67 depends indirectly on claim 50 and so is not obvious for the reasons given above at pages 39-41 in Section VII.B.2.a. with respect to claim 50. The claim is not obvious for the additional reason that neither Safabash et al. nor Miskinyar discloses a trigger releasing a plunger by manual deformation of the housing. As mentioned above in Section VII.A.1.a, "deform" means to alter the shape of by stress and so the button 33 of Miskinyar is not deformable. Similarly, the button 508 of Safabash et al. is also not deformable. Since there is no reason given by the Examiner, Safabash et al. or Miskinyar to use the recited deformable housing, a *prima facie* case of obviousness has not been established and so the rejection is improper and should be reversed.

e. Claims 71 and 88

Claims 71 and 88 were rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar. Appellants traverse the rejection. In particular, claims 71 and 88 depend indirectly on claim 50 or claim 72 and

so are not obvious for the reasons given above at pages 40-42 in Section VII.B.2.a. with respect to claim 50. The claims are not obvious for the additional reason that neither Safabash et al. nor Miskinyar discloses a cover allowing through-flow of a sterilizing agent. While Miskinyar discloses tapes 72 and 80 there is no disclosure that they allow through-flow. Since there is no reason given by the Examiner, Safabash et al. or Miskinyar to use the recited cover, a *prima facie* case of obviousness has not been established and so the rejections are improper and should be reversed.

f. Claim 82

Claim 82 was rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar. Appellants traverse the rejection. In particular, claim 82 depends directly on claim 72 and so is not obvious for the reasons given above at pages 39-41 in Section VII.B.2.a. with respect to claim 72. The claim is not obvious for the additional reason that Safabash et al. and Miskinyar do not disclose manual engagement areas for manual deformation of the device housing. As mentioned previously in Sections VII.A.1.a and VII.B.2.d, button 33 of Miskinyar and button 508 of Safabash et al. are not deformable and so it follows that Safabash et al. and Miskinyar do not provide reasons to use the recited manual engagement areas. Accordingly, the rejection is improper and should be reversed.

g. Claim 83

Claim 83 was rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar. Appellants traverse the rejection. In

particular, claim 83 depends directly on claim 82 and so is not obvious for the reasons given above at page 43 in Section VII.B.2.f. with respect to claim 82. The claim is not obvious for the additional reason that Safabash et al. and Miskinyar do not provide reasons to use manual engagement areas for manual deformation of the device housing that are diametrically opposed on the device housing and peripherally offset with respect to the lock. Accordingly, the rejection is improper and should be reversed.

h. Claim 84

Claim 84 was rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar. Appellants traverse the rejection. In particular, claim 84 depends directly on claim 83 and so is not anticipated for the reasons given above at pages 43-44 in Section VII.B.2.g. with respect to claim 83. The claim is not obvious for the additional reason that Safabash et al. and Miskinyar do not provide a reason to use manual engagement areas for manual deformation of the device housing that are diametrically opposed on the device housing and peripherally offset about 90° with respect to the lock. Accordingly, the rejection is improper and should be reversed.

i. Claim 85

Claim 85 was rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar. Appellants traverse the rejection. In particular, claim 85 depends directly on claim 83 and so is not obvious for the reasons given above at pages 43-44 in Section VII.B.2.g. with respect to claim 83. The claim is

not obvious for the additional reason that Safabash et al. and Miskinyar do not provide a reason to use fingertip size manual engagement areas for manual deformation of the device housing that are diametrically opposed on the device housing and peripherally offset with respect to the lock. Accordingly, the rejection is improper and should be reversed.

j. Claim 89

Claim 89 was rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar. Appellants traverse the rejection. In particular, claim 89 depends indirectly on claim 50 and so is not obvious for the reasons given above at pages 39-41 in Section VII.B.2.a. with respect to claim 50. The claim is not obvious for the additional reason that neither Safabash et al. nor Miskinyar discloses a cover including an upstanding cylinder for surrounding at least a portion of the insertion needle. The Examiner at page 4 of the Office Action has asserted that it would have been obvious to use the tapes 72 and 80 of Miskinyar. However, such tapes do not include a hollow for receiving a part of the insertion needle. Since there is no reason given by the Examiner, Safabash et al. or Miskinyar to use the cover recited in claim 89, a *prima facie* case of obviousness has not been established and so the rejection is improper and should be reversed.

k. Claims 90-92 and 100

Claims 90-92 and 100 were rejected in the Office Action under 35 U.S.C. § 103 as being obvious in view of Safabash et al. and Miskinyar. Appellants traverse the

rejection. In particular, independent claim 90 recites "sterilizing said insertion set by flowing a sterilizing agent through said membrane into an interior of said injector device housing" and independent claim 100 recites "sterilizing said insertion set within said injector device housing. Neither Safabash et al. nor Miskinyar discloses flowing a sterilization agent or sterilizing an insertion set. There is no reason given in Safabash et al. or Miskinyar to flow a sterilization agent in the manner recited in claim 90 or sterilize an insertion set per claim 100. Accordingly, the rejections are improper and should be reversed.

Claims 91 and 92 depend directly on claim 90 and so their rejections should be reversed for the reasons given above with respect to claim 90. For the reasons given above, Appellants respectfully submit that the rejections should be reversed and the claims should be allowed.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

50. An injector device assembly comprising:

a sterile insertion set with a housing and a hollow cannula;

a device housing, said insertion set positioned removably from and within said device housing;

a plunger received within said device housing for movement between an advanced position and a retracted position, said cannula being transcutaneously placed upon movement of the plunger from the retracted position to the advanced position, said insertion set being separable from said plunger;

said device housing having a forward end defining a surface of placement against the skin of a patient; and

a cover member covering an opening defined in said forward end and removably connected to a portion of said device housing, said cover member and said device housing assuring sterile conditions of said insertion set within said device housing prior to removal of said cover member.

51. The injector device assembly of claim 50, said injector device including an insertion needle extending through said hollow cannula and being in frictional engagement with said hollow cannula.

52. The injector device assembly of claim 50, said insertion set being an infusion set, said insertion set housing including an adhesive layer for adhering said insertion set housing to the skin of a patient.

53. The injector device assembly of claim 50, said insertion set being a glucose sensor.

54. The injector device assembly of claim 51, said insertion needle being secured to said plunger by a stable connection preventing loss of the insertion needle during use of the device.

55. The injector device of claim 54, said insertion needle being secured to said plunger by press-fit.

56. The injector device assembly of claim 50, including a trigger for releasably retaining said plunger in the retracted position, the trigger being operable to release the plunger for movement with a controlled force and speed toward the advanced position.

57. The injector device assembly of claim 51, said plunger including a support structure for reception and support of said insertion set, said support structure being

removable from said insertion set while maintaining a transcutaneous placement of said insertion needle.

58. The injector device assembly of claim 50, indicia relating to the shelf life of said assembly being on said cover member.

59. The injector device assembly of claim 50, said plunger being in said advanced position prior to first time removal of said cover member.

65. The injector device assembly of claim 51, wherein said removable cover is member includes a hollow for receiving a part of said insertion needle when said plunger is in said advanced position.

66. The injector device assembly of claim 50, said cover being repositionable subsequent to removal of said insertion set.

67. The injector device assembly of claim 56, said trigger releasing said plunger by manual deformation of said housing.

68. The injector device assembly of claim 56, said insertion set including tubing for delivery of medication to said hollow cannula, said housing including an annular space for accommodating said tubing.

69. The injector device assembly of claim 50, said device housing including a releasable cover at a rearward end of said device housing.

70. The injector device of claim 69, said releasable cover at said rearward end being a membrane.

71. The injector device of claim 70, said releasable cover allowing through-flow of a sterilizing agent into said device housing with said insertion set.

72. An injector device assembly, comprising:

a sterile insertion set with a housing and a hollow cannula, a molded device housing, said insertion set positioned within said device housing for delivery of said sterile insertion set to a patient;

a molded plunger received within the device housing for movement between an advanced position and a retracted position;

a lock for releasably locking said plunger in said retracted position, said housing being manually deformable to effect release of said plunger;

a spring for urging the plunger from the retracted position towards the advanced position, said insertion set being separable from said plunger after placement of said cannula;

said cannula being transcutaneously placed upon movement of the plunger from the retracted position to the advanced position;

said housing having a forward end defining a surface for placement against the skin of a patient with the device housing in a predetermined orientation relative to the patient's skin; and

a removable cover member covering an opening defined in said forward end and connected to a portion of said device housing;

said cover member and said device housing assuring sterile conditions of said separable insertion set within said device housing prior to removal of said cover member.

78. The injector device assembly of claim 72, wherein said insertion set is an infusion set.

79. The injector device assembly of claim 72, wherein said insertion set is a glucose sensor.

80. The injector device assembly according to claim 72, wherein said insertion set includes an insertion needle that is substantially non-detachably secured to said plunger.

81. The injector device assembly of claim 80, wherein said insertion needle is hollow and has a lateral opening near said plunger.

82. The injector device assembly of claim 72, including manual engagement areas for the manual deformation of said housing to effect said release of said plunger.

83. The injector device assembly of claim 82, said manual engagement areas being diametrically opposed on said housing and being peripherally offset with respect to said lock.

84. The injector device assembly of claim 83 wherein said manual engagement areas are offset about 90°.

85. The injector device assembly of claim 83, said manual engagement areas being of fingertip size.

86. The injector device assembly of claim 72, said device housing including a releasable cover at a rearward end of said device housing.

87. The injector device of claim 86, said releasable cover at said rearward end being a membrane.

88. The injector device of claim 87, said releasable cover allowing through-flow of a sterilizing agent into said device housing with said insertion set.

89. The injector device assembly of claim 51, wherein said cover includes an upstanding cylinder for surrounding at least a portion of said insertion needle.

90. A method for making an injector device assembly comprising the steps of:

providing an injector device housing, said injector device housing having a movable plunger and providing an insertion set, said insertion set having an insertion set housing and a hollow cannula;

placing said insertion set within said injector device housing;

connecting at least one releasable cover to at least a portion of said injector device housing to seal said insertion set within said injector device housing, said cover comprising a membrane; and

sterilizing said insertion set by flowing a sterilizing agent through said membrane into an interior of said injector device housing.

91. The method of claim 90, said device housing having a forward end defining a surface of placement against the skin of a patient with the device housing in a predetermined orientation relative to the patient's skin, said releasable cover member covering said forward end.

92. The method of claim 90, said device housing including a releasable cover at a rearward end of said housing.

93. An injector device for transcutaneously placing at least a portion of a cannula of a removable medical device through the skin of a patient, said injector device comprising:

a generally cylindrically shaped housing having a cavity formed therein, said housing including a forward end, said forward end defining a generally planar surface for placement against the skin of the patient;

a carrier member adapted for at least partial reception in said cavity, said carrier member comprising at least one piercing member substantially non-detachably secured to said carrier member;

a drive for urging movement of said carrier member relative to said housing, said drive extending at least partially around at least a portion of said carrier member; and

a releasable cover member covering said forward end, said cover member comprising an upstanding portion defining a bore;

wherein said at least one piercing member is adapted to receive said removable medical device.

94. The injector device of claim 93, wherein said upstanding portion surrounds a portion of the needle.

95. The injector device of claim 93, wherein said upstanding portion is cylindrically shaped.

96. The injector device of claim 93, wherein said cover member and said housing are configured to provide sterile conditions for the medical device prior to removal of said cover member.

97. An injector device assembly comprising:

a sterile insertion set comprising a housing and a hollow cannula;

a device housing having a cavity formed therein, said insertion set positioned removably from and within said device housing;

a plunger having a piercing member connected to the plunger and positioned at least partially within said cavity, said piercing member extending at least partially through said cannula of said insertion set and said piercing member configured to move said insertion set toward the skin of a patient; and

a cover removably connected to a portion of said device housing, said cover accommodating a part of said piercing member, said cover and said device housing assuring sterile conditions of said insertion set within said device housing prior to removal of said cover.

98. The injector device assembly of claim 97, wherein said cover connects to and extends partially along a side wall at said forward portion of said device housing.

99. The injector device assembly of claim 97 wherein said cover is removably connected to said portion of said device housing by snap engagement.

100. A method for providing an injector device assembly having a sterile insertion set provided within an injector device housing, the method comprising:

providing an injector device housing, said injector device housing having a movable plunger and a piercing member connected to the plunger;

providing an insertion set, said insertion set having an insertion set housing and a hollow cannula;

placing said insertion set within said injector device housing so that said piercing member extends at least partially through said cannula;

connecting at least one removable cover to a portion of said injector device housing to cover an opening defined in said injector device housing and to seal said

insertion set within said injector device housing, the cover accommodating a part of said piercing member; and

sterilizing said insertion set within said injector device housing.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.